



# UNITED STATES PATENT AND TRADEMARK OFFICE

BT

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,582	08/17/2000	Arnd Baumann	205970	4666

23460 7590 03/10/2006

LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6780

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1649

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 09/640,582	<b>Applicant(s)</b> BAUMANN ET AL.	
	<b>Examiner</b> Michael Brannock	<b>Art Unit</b> 1649	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): see attached.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 3 and 16-18.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☒ Other: PTO-892.

**Attachment to Advisory Action**

***Status of Application: Claims and Amendments***

Applicant is notified that the amendments put forth on 12/19/06, have been entered in full.

***Response to Amendment***

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

**Maintained Rejections:**

Claims 3 and 16-18 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, as set forth in the prior Office Action.

Claims 3 and 16-18 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues that similar ion channels are known to be involved in cardiovascular, nociception, or psychiatric disorders and that subsequent research has born-out the fact that the instant HNC2 is involved in cardiac pace-making as well as epilepsy. Applicant cites post-filing date work by Qu et al., Plotnikov et al., , Zicha et al., and Ludwig et al., This argument has been fully considered but not deemed persuasive. The issue is that it is was not known or taught what particular disorders a polynucleotide of SEQ ID NO: 1 would be involved in, based on its sequence alone at the time of filing. As set forth previously, many ion channels are known in the

Art Unit: 1649

art that have high sequence homology with the instant SEQ ID NO: 1, but the functions of these channels, and the disorders they have shown to be involved in are completely disparate, there is no nexus between any sequence identity and any disorder, see page 10 of the prior Office action.

Each of the above references has been carefully examined by the examiner, and it is concluded that it is this type of extensive research and investigation, e.g. that of Qu et al., Plotnikov et al., Zicha et al., and Ludwig et al., that the instant specification simply invites the skilled artisan to embark on in order to try to find a way to use the polypeptide and polynucleotide of the instant invention. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

The instant claims are drawn to a polypeptides and polynucleotide of undetermined function or biological significance at the time of filing. One skilled in the art at the time the invention was made, having the specification as a guide as well as full knowledge of the state of the art, would not know how to use the polypeptides and polynucleotides in a way that constitutes a substantial utility. Ludwig et al., EMBO Journal 22(2)216-224, 2003, cited by

Art Unit: 1649

applicant, provide instruction as to the state of the art regarding HCN family members at the time of filing. In column two of page 216, Ludwig discuss the theoretical involvement of HCN family members in pacemaker activity in cardiac cells as well a possible role as general determinates of neuronal excitability and plasticity. However, Ludwig et al. stress that “it is well established that a number of other ion channels contribute to the above-mention functions” and “the specific physiologic relevance of  $I_h$  (HCN family members) to these functions remains unknown”. Further, Ludwig et al. point-out that, “for example, the role of  $I_h$  in pacemaking activity, especially of the sinoatrial node, is controversial. It has been argued that these channels do not contribute to cardiac automaticity for several reasons”, e.g. their activation threshold overlaps only slightly with the maximum diastolic potential. Thus, the physiologic significance of HCN family members, in general, has not been determined; and, as to any specific function of any particular family member, e.g. the instant HCN2, Ludwig et al. teach “the contribution of the individual isoforms to the proposed functions of  $I_h$  is unknown.

Thus, the skilled artisan appreciates that the specification provides only a starting point for further research and investigation into the actual physical properties of the HCN2 in the hope that a particular use for it can be found. Such a starting point for further research regarding the properties of the claimed polynucleotide and encoded polypeptide does not constitute a substantial utility as required by 35 U.S.C. § 101. And nor does such an invitation constitute an enabling disclosure such that the skilled artisan would know how to use the polynucleotide as required under 35 U.S.C. § 112, first paragraph.

Art Unit: 1649

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



March 1, 2006



**ELIZABETH KEMMERER  
PRIMARY EXAMINER**